

**REMARKS**

A check for the requisite fee for filing the RCE and for a three-month extension of time accompanies this response. Any fee that may be due in connection with this paper or with this application may be charged to deposit Account No. 50-1213. If a Petition for extension of time is needed, this paper is to be considered such a Petition. Applicant respectfully requests reconsideration of the above-captioned application in view of the foregoing amendments and the following remarks.

In the final office action mailed July 18, 2003, the Examiner rejected claim 52 under 35 U.S.C. §112, first paragraph. Claims 25-27, 31-33, and 52 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,957,949 to Leonhardt in view of U.S. Patent No. 5,411,552 to Andersen. Pursuant to this paper, Applicant has amended claims 25 and 52 and has added new claim 53. Applicants respectfully request reconsideration of the application in view of the foregoing amendment and the following comments.

**Rejection Under 35 U.S.C. §112 Has Been Overcome**

In the office action mailed July 15, 2003, the Examiner rejected claim 52 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. In an Advisory Action mailed September 9, 2003, the examiner indicated that applicant has overcome the rejection under 35 U.S.C. §112. Accordingly, applicant respectfully submits that all claim are in compliance with 35 U.S.C. §112.

**Rejection Under 35 U.S.C. §103(a)**

Claims 25-27, 31-33, and 52 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,957,949 to Leonhardt in view of U.S.

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Patent No. 5,411,552 to Andersen. However, Applicant respectfully submits that the claims recite subject matter that is neither taught nor suggested by either Leonhardt or Andersen, both alone and in combination. For example, independent claim 25 recites the step of permitting the frame to self-expand within the pulmonic passageway sufficiently to anchor the flow control device within the pulmonic passageway. Both Leonhardt and Andersen fail to teach or suggest a flow control device that self-expands sufficiently to anchor the flow control device within the pulmonic passageway. Accordingly, Applicants respectfully submit that the rejection of claims 25-27, 31-33, and 52 should be withdrawn.

Leonhardt describes a valve stent 20 comprised of three elements, including a stent 26, a biological valve 22, and graft material 24. Leonhardt's stent 26 is self-expanding. See Leonhardt, col. 5, line 47. However, when the valve stent 20 is deployed in a body passageway, the stent 26 does not self-expand sufficiently to anchor the valve stent 20 in the passageway. Rather, Leonhardt requires that an expansion balloon 154 be used to anchor the valve stent in the body passageway. As stated in Leonhardt, after the valve stent is positioned in the body passageway, "[e]xpansion balloon 154 is then inflated to a pressure sufficient to hold the distal end of valve stent 20 secure against the living tissue as seen in FIG. 9C. This ensures proper placement is maintained during the remainder of the deployment procedure and allows valve stent to mold itself quickly into the living tissue at the placement site and achieve a patent seal." (See Leonhardt, col. 11, lines 3-9 (emphasis added).) Leonhardt provides no teaching or suggestion of a device that self-expands sufficiently to anchor in a body passageway.


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Andersen also fails to teach or suggest a flow control device that self-expands sufficiently to anchor in a body passageway. Andersen describes a valve prosthesis for implantation in the body. Unlike the method recited in claim 25, deployment of the Andersen valve prosthesis requires the use of an expansion balloon 13 to expand the prosthesis sufficient to anchor the prosthesis in a body passageway. (See Andersen, col. 6, lines 20-44, FIGS. 5-7.) Although Andersen describes an embodiment of the valve prosthesis that self-expands (see col. 7, lines 17-23), Andersen makes no mention of the valve prosthesis self-expanding sufficiently to anchor in the body passageway.

In view of the foregoing, applicant respectfully submits that the rejection of claim 25 under 35 U.S.C. §103(a) should be withdrawn. Claims 26-27, 31-33, 52, and 53 depend from claim 25 and all of these claims recite subject matter that is neither taught nor suggested by the cited art. In addition, these claims are patentable in view of their dependence on claim 25.

If the Examiner has any questions regarding the foregoing, she is cordially invited to contact the undersigned so that any such matters may be promptly resolved.

Respectfully submitted,  
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